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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/308,218	09/19/1994	MARC ALIZON	3495.001019	4831

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FINNEGAN, HENDERSON, FARABOW, GARRETT &  
DUNNER LLP  
1300 I STREET, NW  
WASHINGTON, DC 20005

EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/17/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/308,218

Applicant(s)

ALIZON ET AL.

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 September 1995.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status***

1. This rejection is non-final. It is noted that this application was suspended pending the result of Interference 102,822, which interference was resolved in favor of the other party. Therefore, the Chang et al patent, cited below in the 102 rejections, is properly 102(e) art which cannot be rebutted due to res judicata.
2. Separately, Applicant is requested, in any response to this office action, to submit a copy of the original claims which were submitted for interference, in order to determine which claims, if any, should be cancelled under 37 CFR 1.663.

### ***Double Patenting***

3. Claims 13 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of copending Application No. 08/475,822.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to the identical products, the HIV ORF R, with the copending claim 17 simply including reagents for the hybridization reaction. Therefore, claim 17 teaches a composition comprising the product of the HIV ORF-R sequence. Thus, the claims are obvious one over another because both claims are drawn to the same element. In fact, the current claim is more generic than claim 17 of the copending application 08/475,822 and the narrower species claim 17 might be deemed to anticipate and necessarily render obvious this broader generic claim.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al (U.S. Patent 6,001,977).

The claims utilize the open "having" language which permits the inclusion of additional elements. "Having" is interpreted as being of identical scope to "comprising".

Chang teaches in vitro diagnostic methods for detecting the presence or absence of HIV-1 virus in a biological sample (column 9, lines 25-62) comprising:

contacting said biological sample with a nucleic acid probe of HIV-1 selected from the HIV sequence (column 9, lines 25-62 and column 10, line 65 to column 11, line 32),

where the specific sequence is disclosed as SEQ ID NO: 4, for example (columns 19-28).

And detecting the formation of hybrids in the biological sample (column 9, lines 25-62).

Chang further teaches the compositions of these nucleic acids (column 9, lines 25-62) as well as HTLV-I and II negative control sequences (column 9, lines 25-62).

The alignment of the Query HIV sequences of Chang and the subject sequences of the present application in the region of HIV ORF-R are presented below.

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## Alignment

Query: gacagggcttggaaggattttgctataaga 8153  
|||||  
Sbjct: gacagggcttggaaggattttgctataaga 8354

Query: 8154 tgggtggcaagtgggtcaaaaagtagtgtggttgatggcctgctgtaagggaaagaatga 8213  
|||||  
Sbjct: 8355 tgggtggcaagtgggtcaaaaagtagtgtggttgatggcctactgtaagggaaagaatga 8414  
orfF 11 M G G K W S K S S V V G W P T V R E R M

Query: 8214 gacgagctgagccagcagcagatggggtgggagcagcatctcgagacctagaaaaacatg 8273  
|||||  
Sbjct: 8415 gacgagctgagccagcagcagatggggtgggagcagcatctcgagacctggaaaaacatg 8474  
orfF 31 R R A E P A A D G V G A A S R D L E K H

Query: 8274 gagcaatcacaagtagcaacacagcagctaacaatgctgattgtgcctggctagaagcac 8333  
|||||  
Sbjct: 8475 gagcaatcacaagtagcaatacagcagctaccaatgctgcttgtgcctggctagaagcac 8534  
orfF 51 G A I T S S N T A A T N A A C A W L E A

Query: 8334 aagaggaggaggaggtgggttttccagtcacacctcaggtacctttaagaccaatgactt 8393  
|||||  
Sbjct: 8535 aagaggaggaggaggtgggttttccactcacacctcaggtacctttaagaccaatgactt 8594  
orfF 71 Q E E E E V G F P L T P Q V P L R P M T

Query: 8394 acaaggcagctgtagatcttagccactttttaaaagaaaaggggggactggaaggggctaa 8453  
|||||  
Sbjct: 8595 acaaggcagctgtagatcttagccactttttaaaagaaaaggggggactggaaggggctaa 8654  
orfF 91 Y K A A V D L S H F L K E K G G L E G L

Query: 8454 ttcactccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8513  
|||||  
Sbjct: 8655 ttcactccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8714  
orfF 111 I H S Q R R Q D I L D L W I Y H T Q G Y

Query: 8514 tccctgattagcagaactacacaccagggccagggatcagatatccactgacctttggat 8573  
|||||  
Sbjct: 8715 tccctgattggcagaactacacaccagggccaggggtcagatatccactgacctttggat 8774  
orfF 131 F P D W Q N Y T P G P G V R Y P L T F G

Query: 8574 ggtgctacaagctagtagtaccagttgagccagagaagttagaagaagccaacaaaggagaga 8633  
|||||  
Sbjct: 8775 ggtgctacaagctagtagtaccagttgagccagataaggtagaagaggccaataaaggagaga 8834  
orfF 151 W C Y K L V P V E P D K V E E A N K G E

```
Query: 8634 acaccagcttggttacaccctgtgagcctgcatggaatggatgaccgagagagagaagtgt 8693
          |||
Sbjct: 8835 acaccagcttggttacaccctgtgagcctgcatggaatggatgaccctgagagagagaagtgt 8894
orfF 171 N T S L L H P V S L H G M D D P E R E V

Query: 8694 tagagtggaggtttgacagccgcctagcatttcacatggcccgagagctgcatccgg 8753
          |||
Sbjct: 8895 tagagtggaggtttgacagccgcctagcatttcacatggcccgagagctgcatccgg 8954
orfF 191 L E W R F D S R L A F H H V A R E L H P

Query: 8754 agtacttcaagaactgc
          |||
Sbjct: 8955 agtacttcaagaactgc
orfF 211 E Y F K N C
```

It is noted that with regard to, for example, the sequence region of ORF-R claimed in claim 13, there are 14 nucleotide differences between the sequences. It is noted that the art recognizes that sequencing errors occur in a range between 0.3 % and 2.5%, as evidenced by Richterich (Genome Research (1998) 8:251-259). However, these error rates are determined using technology that was significantly more advanced than that in 1984, when sequencing error rates were likely significantly higher. In the 657 nucleotide sequence which is the sequence of claim 13, 14 errors would represent approximately a 2.1% error rate. Thus, these sequences are identical within the error range available and the anticipation rejection is proper.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman  
Primary Examiner  
Art Unit 1637

May 15, 2002